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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,675	07/23/2003	Rod Berube	00167-362002	6691
26166 7590 09/18/2007 FISH & RICHARDSON P.C. SMITH & NEPHEW, INC. 150 Minuteman Road Andover, MA 01810			EXAMINER WOO, JULIAN W	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 09/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,675

Applicant(s)

BERUBE ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55, 57-68, 81-88 and 92-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 55, 57-68, 81-88 and 92-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 81, 82, 84-88, 99, and 100 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowald (5,425,766). Bowald discloses, in figure 1 and in col. 3, lines 34-49 and col. 5 line 47 to col. 6, line 12; a bioabsorbable, polymeric tissue fastener including a hollow shaft (2 and 3 combined) having a generally rigid member (4) disposed thereon; a generally rigid solid tissue engaging head (8) having a maximum transverse cross-sectional length longer than the maximum cross-sectional length of the shaft, a region of the shaft (2) being relatively flexible to provide transverse flexibility and longitudinal extensibility (an inherent property of elastic, polymeric materials formed into braided, twined, knit, or woven "elongate members") and being formed of a mesh (3) between the head and the member, where the region comprises substantially an entire length of the shaft, where the shaft defines a first passage or a substantially void interior passage (which accommodates at least a guidewire (10)), where the rigid member defines a second passage or a substantially void interior passage (which also accommodates the guidewire) along an entire length of the rigid member, where the head and member are molded onto the mesh, and where the member comprises at least one barb (external screw threads).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 55, 57-68, 83, 95-98, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowald (5,425,766) in view of Coleman et al. (4,469,101).

Bowald discloses the invention substantially as claimed. Bowald discloses a tissue fastener including, inter alia, a shaft (2 and 3 combined), a generally rigid member (4) defining a second passage that is a substantially void interior passage, and a generally rigid tissue engaging head (8) having a maximum transverse cross-sectional length longer than the maximum cross-sectional length of the shaft and having a maximum longitudinal cross-sectional length (thickness) along a longitudinal axis shorter than the maximum transverse cross-sectional length of the head, where substantially an entire length of the shaft extending from the member to the head is formed of a mesh (i.e., according to col. 3, lines 28-49 and col. 5, lines 47-54; the mesh comprises "net;"

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"knitted, woven or braided structures," or a "net-shaped or knitted structure" and a "net-shaped outer covering") providing transverse flexibility and longitudinal extensibility to render the head movable with respect to the shaft, where the shaft is hollow and defines a first or a substantially void interior passage that is open at the distal end of the shaft, and where the head has a flat distal surface and a toothed distal surface (at elements 9). However, Bowald does not specifically disclose that the shaft (e.g., the "net" or "net-shaped structure" and/or a "net-shaped outer covering") is formed of a woven mesh.

Coleman et al. teach, at least in figures 1 and 2 and col. 2, line 64 to col. 3, line 19 and col. 4, lines 56-66; a bioabsorbable device (10) analogous to the shaft of Bowald, where the device comprises a woven mesh that is transversely flexible and longitudinally extensible. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Coleman et al., to form the shaft of Bowald out of a woven mesh. Such a structure is strong and flexible, can carry loading upon the shaft, and would promote tissue healing and growth.

5. Claims 55 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gourd (5,061,137) in view of Lewis et al. (5,382,257). Gourd discloses the invention substantially as claimed. Gourd discloses, at least in figures 1-4 and col. 4, lines 20-68 and col. 5, line 66 to col. 6, line 22; a tissue fastener including a shaft (10), a generally rigid member (6) disposed at an end of the shaft, and a generally rigid, tissue engaging head (4 and 8 combined) disposed at an end of the shaft and having a maximum longitudinal cross-sectional length along the longitudinal axis (i.e., the thickness of element 8) shorter than the maximum transverse cross-sectional length of

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the head (at 8), where substantially an entire length of the shaft extends from the member to the head and provides transverse flexibility and longitudinal extensibility (i.e., the shaft may comprise a resilient or elastomeric material having "suitable compression and elongation characteristics"), and where the member (6) includes at least one barb (13). However, Gourd does not disclose that the shaft is formed of a woven mesh.

Lewis teaches, in fig. 1A and in col. 1, lines 44-47; col. 2, lines 32-39; and col. 4, lines 45-47; a tissue fastener (21) comprising a woven mesh. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Lewis, to form Gourd's shaft from a woven mesh. Such a structure would form a strong yet supple shaft that can withstand the stresses and strains of movement of the head with respect to the shaft with less risk of catastrophic failure.

6. Claims 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gourd in view of Lewis et al. as applied to claim 58 above, and further in view of Fucci et al. (6,290,702). Gourd in view of Lewis et al. discloses the invention substantially as claimed. Gourd particularly discloses, in col. 4, lines 20-33, that the rigid member (6) includes molded barbs that may be "slotted or staggered" and be configured to "best serve the strength requirements of the particular application in a manner well known in the fastener arts. However, Gourd in view of Lewis et al. does not disclose that the at least one barb includes a flat, inclined exterior surface that slopes outwardly as the at least one barb extends proximally towards the tissue engaging head. Fucci et al. teach, in figure 1 and in col. 4, lines 31-59; a fastener including staggered barbs (e.g., at row 20) each having a flat, inclined exterior surface that slopes

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outwardly as the barb extends proximally towards a tissue engaging head. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Fucci, et al., to modify the barbs of the Gourd in view of Lewis et al., so that they each have a flat, inclined exterior surface that slopes outwardly as the at least one barb extends proximally towards the tissue engaging head. Such a barb with a flat, inclined surface would not only ease insertion of the rigid member into tissue, it would enhance the holding strength of the member by being relatively rigid and by enabling the flow of tissue or material at a proximal face of the barb.

Response to Amendment

7. The objection to claim 81 is hereby withdrawn, in view of the amendment.

Applicant's arguments with respect to claims 55, 57-68, and 83 have been considered but are moot in view of the new ground(s) of rejection.

With respect to arguments regarding the rejections of claims based on the Bowald reference: Bowald indeed discloses a shaft or a region of the shaft having inherent longitudinal extensibility. That is, the shaft is formed of an elastic, polymeric material; and the shaft can be made of braided, twined, knit, or woven "elongate members" of the elastic material, where tension on the shaft would inherently cause the filaments of a braid, twine, or a knit or woven structure to slip against each other, resulting in longitudinal extension.

With respect to arguments regarding the rejections based on the Gourd reference: As recited above, Gourd indeed discloses a head having, at element 8, "a

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maximum longitudinal cross-sectional length along the maximum longitudinal axis.” The thickness of element 8 is a dimension “shorter than the maximum transverse cross-sectional length of the head.”

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

September 12, 2007